4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-4644]

Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled "Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization." This guidance finalizes the draft guidance issued December 23, 2015, which provides recommendations to pharmaceutical companies interested in participating in a program involving the submission of emerging manufacturing technology. The program is open to companies that intend to include the technology as part of a regulatory submission including an investigational new drug application (IND), original or supplemental new drug application (NDA), abbreviated new drug application (ANDA) or biologic license application (BLA), or application-associated Drug Master File (DMF) reviewed by the Center for Drug Evaluation and Research (CDER), and where that technology meets other criteria described in this guidance.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2015-D-4644 for "Advancement of Emerging Technology Applications for Pharmaceutical Innovation and

Modernization." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sau L. Lee, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 22, rm. 2128, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-506-9136; or for further information or to submit requests to participate in the program, please use CDER-ETT@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization." FDA is committed to supporting and enabling pharmaceutical innovation and modernization as part of the Agency's mission to protect and promote the public health. While the implementation of emerging technology is critical to advancing product design, modernizing pharmaceutical manufacturing, and improving quality, FDA also recognizes that the adoption of innovative approaches may represent challenges to industry and the Agency.

Issues in pharmaceutical manufacturing have the potential to significantly impact patient care as failures in quality may result in product recalls and harm to patients. Additionally, product failures or facility, equipment, or manufacturing problems are a major factor leading to

disruptions in drug supply. Modernizing manufacturing technology may lead to a more robust manufacturing process with fewer interruptions in production, fewer product failures (before or after distribution), and greater assurance that the drug products manufactured in any given period of time will provide the expected clinical performance. Encouraging development of emerging technology may lead to pharmaceutical innovation and modernization, such as a more robust drug product design and improved manufacturing with better process control, thereby leading to improved product quality and availability throughout a product's lifecycle.

In this program, pharmaceutical companies can, prior to the regulatory submission, submit questions and proposals about the use of specific emerging technology to a group within the FDA Emerging Technology Team (ETT), which includes relevant representation from all FDA pharmaceutical quality functions. The ETT works in partnership with relevant pharmaceutical quality offices and assumes a leadership or co-leadership role for the cross-functional quality assessment team (including review and on-site facility evaluation or inspection) for submissions involving emerging technology.

This guidance finalizes the draft guidance issued December 23, 2015 (80 FR 79907). It provides further clarification on the criteria that the proposed technology needs to meet for its acceptance into the Emerging Technology Program. It also clarifies types of novel technology (e.g., product technology, manufacturing process, and control strategy) that can be covered by the program.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on advancement of emerging technology applications for pharmaceutical innovation and modernization. It does not

establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The information to be included in a meeting request for a product submitted in an IND, BLA, or NDA is approved by OMB control number 0910-0429 ("Guidance for Industry on Formal Meetings Between the FDA and Sponsors or Applicants"). Information to be included in a meeting request for a product submitted in an ANDA is approved by OMB control number 0910-0797 ("Guidance on Controlled Correspondence Related to Generic Drug Development"). The submission of INDs under 21 CFR 312.23 is approved by OMB control number 0910-0014; the submission of BLAs under 21 CFR 601.2 and 601.12 is approved by OMB control number 0910-0338; and the submission of NDAs and ANDAs under 21 CFR 314.50, 314.70, 314.71, 314.94, and 314.97 is approved by OMB control number 0910-0001.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or https://www.regulations.gov.

Dated: September 22, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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